K122006



AUG 6 2012

## 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

### Submitter Information

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Date: July 6, 2012

Trade Name: G-scan Brio

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

### Predicate Device(s)

| Trade Name | Common name | Class | Product code | Manufacturer | K number |
|---|---|---|---|---|---|
| G-scan | System, nuclear magnetic resonance imaging | II | LNH | ESAOTE S.P.A. | K111803 |

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## Device Description

The changes performed on the modified G-scan device (G-scan Brio), with respect to the cleared version – G-scan K111803 – are due to the improvement of the system performance. These modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

1. A new patient table that can be moved manually in the inner/outer direction of the gantry.
2. A new footboard and seat for vertical examinations.
3. A patient table extension.
4. A back support.
5. A new step for patient positioning.
6. A new control panel on the front of the magnet.
7. Upgrading of the hydraulic circuit.
8. Upgrading of the electronics.
9. 4-channels Lumbar spine coils N.17 and 18 introduction, cleared via K110802.
10. A new software release.

## Intended Use(s)

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip, imaging the temporomandibular joint and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

G-scan Brio images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

## Technological Characteristics

The modifications reflected in this Special 510(k) for the G-scan Brio system are to improve system performance. The modifications have not altered the fundamental scientific technology of the unmodified version, G-scan K111803.

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**Performance Data**

Design controls and risk analysis measures were applied to the development of the G-Scan Brio system, along with the following industry performance and safety standards:

- IEC 60601-1:1988 Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-1:2000, Medical Electrical Equip - Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2:2001, General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests
- IEC 60601-1-4:2000, Medical electrical equipment - Collateral standard: Programmable electrical medical systems
- IEC 60601-2-33 (2008), Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
- IEC 62304:2006 Medical device software - Software life cycle processes
- ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing
- ISO 14971:2007 Medical devices - Application of risk management to medical devices
- NEMA MS-1-2008, Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
- NEMA MS 2-2008 Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- NEMA MS 3-2008 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- NEMA MS 5-2010 Determination of Slice Thickness in Diagnostic Magnetic Resonance Images

Non-clinical testing of the G-scan Brio system demonstrated that it met performance requirements and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Esaote, S.p.A
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AUG 6 2012

Re: K122006
Trade/Device Name: G-scan Brio
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH, LLZ and MOS
Dated: July 6, 2012
Received: July 9, 2012

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122006

Device Name: G-scan Brio

Indications for Use:

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs, joints and spinal column. It is intended for imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip, imaging the temporomandibular joint and imaging the cervical spine and the lumbar spine sections as portions of the spinal column.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

(Division Sign-Off)
Division of Radiological Devices
OIVD
510k K122006